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HM22/0723

EXAMINER

PONNALURI, P

| ART UNIT | PAPER NUMBER |
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1627

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Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

Office Action Summary

Application No.

09/448,420

Applicant(s)

Seul et al

Examiner

P. Ponnaluri

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on May 10, 2001
- 2a) ☒ This action is FINAL. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 98-128 is/are pending in the application.
- 4a) Of the above, claim(s) 114, 115, 117-120, and 126 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 98-113, 116, 121-125, 127, and 128 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claims _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are objected to by the Examiner.
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

- 13) ☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).
- a) ☐ All b) ☐ Some* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

*See the attached detailed Office action for a list of the certified copies not received.

- 14) ☒ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

- 15) ☐ Notice of References Cited (PTO-892) 18) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 16) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 19) ☐ Notice of Informal Patent Application (PTO-152)
- 17) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s). _____ 20) ☐ Other: _____

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DETAILED ACTION

1. The amendment D, filed on 5/10/01 has been fully considered and entered into the application.
2. This application is a continuation of PCT/US98/10719, which is a continuation of provisional application 60/047,472.
3. New claims 98-128 have been added, and claims 74-97 have been canceled by the amendment D, filed on 5/10/01.
4. Claims 98-128 are currently pending in this application.
5. During a telephone conversation with Attorney Julie Bowker on 10/11/00 a provisional election was made without traverse to prosecute the invention of group I, claims 74-84 and 86-96; and species nucleotides (for compounds), binding to a probe (for property) and static planar array (for array). Affirmation of this election must be made by applicant in replying to this Office action. Claims 85 and 97 withdrawn from further consideration by the examiner, 37 CFR 1.142(b), as being drawn to a non-elected invention, and claims 82 and 94 withdrawn as being drawn to non elected species.

Applicants in the response filed on 5/10/0, has confirmed the election of group I, claims 74-84, 86-96. And regarding the species election, (applicants have elected 'nucleotides' as compounds of interest on 10/11/00), applicants now want to elect 'oligopeptide' as compound (in the response filed on 5/10/01, page 12) , instead of the elected 'oligonucleotide'. Since applicants have received an action on merits for the elected compound (nucleotide), the new

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election of 'oligopeptide' would not be considered. Thus, in this application only claims drawn to nucleotide compounds (oligonucleotide) are examined.

6. Newly submitted claims 114-115, 117-120 are directed to an invention that is independent or distinct from the invention originally claimed for the following reasons:

the newly added claims are drawn to compounds other than the elected oligonucleotides as compounds. The newly added compounds are structurally and functionally different from the originally elected compounds (oligonucleotides), these claims are withdrawn from further consideration.

Since applicant has received an action on the merits for the originally presented invention, this invention has been constructively elected by original presentation for prosecution on the merits. Accordingly, claims 114-115, 117-120 withdrawn from consideration as being directed to a non-elected invention. See 37 CFR 1.142(b) and MPEP § 821.03.

7. Newly submitted claim 126 is directed to an invention that is independent or distinct from the invention originally claimed for the following reasons: the newly added claim 126 is drawn to a chemically library (a product), which is different from the originally elected (10/11/00) process claims. The product as claimed in new claim 126 can be prepared by well known techniques in the art, and do not require the method of claim 98.

Since applicant has received an action on the merits for the originally presented invention, this invention has been constructively elected by original presentation for prosecution on the

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merits. Accordingly, claim 98 is withdrawn from consideration as being directed to a non-elected invention. See 37 CFR 1.142(b) and MPEP § 821.03.

8. Claims 98-113, 116, 121-125, 127-128 are currently being examined in this application.

9. The abstract filed on 5/10/01 has been entered into the application.

10. In view of applicants arguments filed on 5/10/01, examiner has agreed that the new claims 104-106 (old claims 76-78, 89-91) have support in the PCT application PCT/US98/10719, and in 60/047,472. The objection has been withdrawn and these claims have priority date of 5/23/97 (60/047,472 filing date).

11. In view of applicants arguments filed on 5/10/01, the new matter rejection of new claims 104-106 (old claims 76-78, 89-91) has been withdrawn.

Rejections necessitated by the Amendment

12. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

13. Claim 98 is rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. This is a new matter rejection.

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Claim 98 recites '**M is an integer from at least 2 to about 50**'. The limitation 'M is an integer from at least 2 to about 50' claimed in claim 98 has no clear support in the specification and the claims as originally filed. The specification page 8 (as originally filed) or in claim 74, as pointed out by applicants in the amendment filed on 5/10/01 has no clear support for this limitation. The old claim 74 recites that '**M is an integer from at least 2 to about 25**'. The subject matter claimed in claim 98 broadens the scope of the invention as originally disclosed in the specification.

If applicants disagree, applicant should present a detailed analysis as to why the claimed subject matter has clear support in the specification.

14. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

15. Claims 98-128 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 98 recites the limitation "the coupling and the tagging step" in step (d). There is insufficient antecedent basis for this limitation in the claim.

Claim 98 recites in step f, 'performing an assay capable of indicating that nay compound in the library has a property of interest'. The assay performed is critical or essential for the claimed

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invention. It is not clear what is the property of interest applicants are assaying for, and no assay has been defined. So the claim is vague and indefinite.

Claim 123 is vague and indefinite by reciting 'the compounds remains adsorbed to the solid support', it is not clear what does applicants mean by the recitation ' the compound is cleaved from its solid support.... remains adsorbed to the solid support...', does applicants mean that the compounds are cleaved the solid support but still remain on the solid support. Applicants are requested to clarify.

Claim 123 recites the limitation "the logical connection" . There is insufficient antecedent basis for this limitation in the claim or in claim 98.

Claim 123 is vague and indefinite by reciting 'logical connection', it is not clear what does applicants mean by logical connection. What is logical connection.

Claim 106 recites fluorescent dyes with chemical structures. The second chemical structure in claim 106 (in page 7, of the amendment), **does not have the carboxyl group (-COO- group) on the benzene ring**, which would be required for the fluorescent function of the compound. See the attached marked copy of the claims.

Response to Arguments

16. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

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17. Claims 98-128 (old claims 74-81, 83-84, 86-93, and 95-96) are rejected under 35 U.S.C. 112, second paragraph, for the reasons set forth in the previous office action mailed on 11/7/00.

A) *Applicants response filed on 5/10/01, regarding the phrase 'bit of binary code' has been considered. However, it is not persuasive because "bit" is short hand for binary digit. Thus, bit of binary code is indefinite. Applicants may amend the claim by reciting "tag represents a binary code, and the binary code comprises zero, one".*

B) *Applicants response regarding the 'assay capable of indicating...', has been considered. However, it is not clear what kind of assays are performed. Because it is essential in the method of screening what kind of assay is used in identifying the compound of interest in a library of compounds.*

C) *In the absence of applicants response to the rejection of claim 78 in previous office action, the rejection has been applied to the new claim 106.*

18. Claims (new claims) 98-100, 103, 109-111, 116, 121, 124-125, 127-128^{and} (old claims) 74-75, 79, 80-81, 83-84, 86-87, 92-93 are rejected under 35 U.S.C. 102(b) as being anticipated by WO 93/06121 (Dower et al) for the reasons of record in the previous office action mailed on 11/7/00.

19. Applicant's arguments filed on 5/10/01 regarding the rejection of claims over Dower et al have been fully considered but they are not persuasive.

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Applicants argue that Dower does not anticipate the claimed invention, at least because it does not disclose the step of identifying the compound of interest from a library of compounds that does carried out without removing the beads of interest from the mixture. Applicants arguments have been considered but are not persuasive, because Dower teach a method for identification of beads carrying the compounds of interest while the beads are present in the mixture of beads. The passage applicants are referring to in Dower in page 26, refers to recovering and decoding the identifier tag information. The beads after the receptor screening experiment, the beads are segregated individually. Dower et al teach method for screening synthetic oligomer libraries with receptors (see page 29). The reference teaches that the oligomer library can be synthesized on microscopic beads with identifier tag encoding the oligomer sequence, the microscopic beads are placed in individual compartments, and the oligomers are cleaved from the beads and remain contained in the compartment along with the bead and the attached identifier tags. The bottom surface is coated with receptor (refers to new claims 123-125) (see page 30). So the beads of interest are not operated from the mixture to accomplish the identification.

Applicants argue that Dower does not anticipate the claimed invention, because it does not disclose a binary coding strategy using fluorophore dyes. Applicants arguments have been carefully considered but are not persuasive, because Dower teach the identifier tag may be any recognizable feature, including for example: a microscopically distinguishable shape, size, color (refers to fluorescent) optical density (see page 7). The reference teaches that the identifier tag

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may be differently absorbing or emitting light, and each bead in the library incorporates a variety of fluorophores or other light addressable type of molecules, the spectral properties can be changes and store information (see page 21). The reference teaches binary code tagging methods also. Thus, the reference teaches the use of fluorophore dyes binary code method. The rejections have been maintained for the reasons of record.

20. Claims 74-75, 79, 80-81, 83-84, 86-87, 92-93 are rejected under 35 U.S.C. 103(a) as being unpatentable over Still et al (US Patent 5,968,736) for the reasons of record in the previous office action mailed on 11/7/00.

*Applicant's arguments filed on 5/10/01, regarding the rejection of claims over Still et al have been fully considered but they are not persuasive. Applicants argue that Still does not teach or suggest that the identification of the compounds of interest may be carries out without removing the beads from the mixture and without cleaving the identifier tag from the beads for further analysis. Applicants arguments have been considered but are not persuasive, because Still et al teach in column 17, after the synthesis of product is complete, they are screened for a desired property either after detachment of the ligand from the bead **or while still attached**. The reference teaches that **the beads are incubated** in aqueous buffer with mouse monoclonal antibody Y. Thus, the reference does teach that the beads are in mixture and are not separated or the compound is cleaved from the bead. Thus the rejections of record have been maintained.*

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21. **Claims 98-103, 109-113, 116, 121-125, 127-128 (added on 5/10/01) (old claims 74-77, 79-81, 83-84, 86-90, 92-93, 95) are rejected under 35 U.S.C. 103(a) as being unpatentable over Dower (WO 93/06121) in view of Metzker et al (US patent 5,728,529) for the reasons of record in the previous office action mailed on 11/7/00.**
22. Applicant's arguments filed on 5/10/01 regarding the rejection of claims over Dower in view of Metzker have been fully considered but they are not persuasive.

Applicants argue that Dower does not teach or suggest the decoding of the tags without removing the beads of interest from the mixture. Applicants arguments have been considered but are not persuasive, because the limitation 'the decoding of the tags without removing the beads of interest from the mixture' is not present in the instant claims. The claim recites that identifying the compound by optical interrogation, and said optical interrogation is carried out without isolating the solid support of interest from other solid support. **That is interpreted as the bead with the compound of interest is identified from a library using optical interrogation, which is different from applicants arguments that "the decoding of the tags without removing the beads of interest from the mixture". The decoding the tag is different from the optical interrogation of fluororophore tags.** The reference teaches that after the bead with the compound of interest is identified, the bead is separated out to decode the tag. In response to applicant's argument that the references fail to show certain features of applicant's invention, it is noted that the features upon which applicant relies (i.e., the decoding of the tags without removing the beads of interest from the mixture) are not recited in the rejected claim(s).

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Although the claims are interpreted in light of the specification, limitations from the specification are not read into the claims. See *In re Van Geuns*, 988 F.2d 1181, 26 USPQ2d 1057 (Fed. Cir. 1993). The rejections of record have been maintained for the reasons of record.

23. No claims are allowed.

24. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to P. Ponnaluri whose telephone number is (703) 305-3884. The examiner

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can normally be reached on Monday to Thursday from 6.30 AM to 4.00 PM. The examiner can also be reached on alternate Fridays.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jyothsna Venakt, Ph.D., can be reached on (703) 308-2439. The fax phone number for the organization where this application or proceeding is assigned is (703) 308-4242.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.

P. Ponnaluri
Patent Examiner
Technology Center 1600
Art Unit 1627
16 July 2001



PADMASHRI PONNALURI
PRIMARY EXAMINER